In re Application of: Gad KEREN et al
Serial No.: 09/839,643
Filed: April 20, 2001
Office Action Mailing Date: July 10, 2009

Examiner: NGUYEN Camtu Tran
Group Art Unit: 3772
Attorney Docket: 34948

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 49-51, 59, 60, 68-73, 78, 84, 86-90, 92 and 97-108 are pending in the application. Claim 62 has been withdrawn from prosecution. Claims 49-51, 59, 60, 68-73, 78, 84, 86-90, 92 and 97-108 are rejected.

Claims 49 and 84 have now been amended. Claim 90 has now been cancelled. Claims 61, 63-67, 74-77, 79-83, 91, 93-96 and 109-112 have been cancelled in a previous response.

Claim Rejections - 35 USC § 102

The Examiner has rejected claims 49-51, 59-61, 63-71, 73-74, 76-79, 84, 86-87, 89, 90, 92, 98-102, 111 and 112 under 35 U.S.C. 102(e) as being anticipated by Bailey et al. (US Patent No. 6,458,153).

The Examiners rejections are respectfully traversed. Claims 49 and 84 have now been amended; claim 90 has now been cancelled rendering moot any rejections with respect to this claim.

In the "response to arguments" section of the official action the Examiner states that "the Bailey et al's CC valve (40) can be used to regulate pressure differential" and points to column 11 lines 13-23 of Bailey et al. as evidence. The Examiner further states that regarding the claimed limitation a shunt positioned within a septum, the Bailey et al. reference discloses its CC valve (40) adapted for use in septal defects, which is known to be positioned within a septum.

Bailey et al. do not describe or suggest the present invention as claimed, since:

(i) configurations of Bailey et al. that enable flow between chambers are only described in the context of valve replacement therapy.

Clearly, flow-enabling configurations (having a valve) are disclosed by Bailey et al. only in the context of therapy designed for replacing natural anatomic valves

present between chambers (mitral valve) or between a chamber and vessel (aortic valve).

The section referenced by the Examiner clearly describes a chamber to chamber configuration which does not involve trans-septal placement, but rather is designed solely for replacement of an anatomic valve positioned between a ventricle and an atria:

"Turning to FIGS. 12A and B there is illustrated the inventive CC stent valve 40 implanted in the position of the mitral valve and excluding the anatomic mitral valve MV. FIG. 12A illustrates the heart during atrial systole in which a positive pressure is applied to the prosthetic mitral valve by contraction of the left atrium LA and the pressure exerted by the blood flow represented by the arrow. The atrial systolic pressure overcomes the bias exerted by the valve arms 24 onto the valve leaflets 26, and causes the valve leaflets 26 to open and release the atrial ejection fraction into the left ventricle. FIG. 12B illustrates that the presence of a negative pressure head across the stent valve 40, i.e. such as that during atrial diastole, causes the biased valve leaflets 26 which are already closed, to further close, and prevent backflow from the left ventricle into the left atrium."

Thus, configurations of Bailey et al. which are designed to allow flow between chambers are only described for use in the context of valve replacement.

(ii) configurations of Bailey et al. which are designed for septal implantation do not enable flow between chambers, since such configurations are designed for correction of septal defects and as such include a septal occluding member.

This is clear from the following:

(column 5 , lines 30-32):

*... or for **septal defect repair** where **a septal occluding member** is substituted for the flow regulator valve flaps."*(emphasis added)

(column 11, lines 28-32):

"In accordance with another preferred embodiment of the invention, the CC configuration may be adapted for use in repairing septal defects. By simply ***substituting*** *a membrane for the valve leaflets 26, the lumen of the stent body member 12 is* ***occluded****. The CC stent valve 40 may be delivered endoluminally and placed into a position to subtend a septal defect and deployed to* ***occlude*** *the septal defect."*
(emphasis added)

Clearly, Bailey et al. describe configurations designed for septal placement in which the flow-enabling element (valve) is replaced with an occluding element. This prior art reference does not describe nor mention a trans-septal configuration which enables flow between chambers. In fact, this reference **only** teaches correction of septal defects via an occluded device configuration (as is accepted in the art).

In that respect, Applicant strongly believes that Bailey et al. teach away from the present configurations which are designed for accomplishing the exact opposite of the device of Bailey et al., i.e. creating a flow conduit between adjacent atria.

With respect to claims covering the present device, such claims clearly define the device as having a combination of flow-through capabilities and septal anchoring capabilities. The configurations of Bailey which include flow through capabilities (valve configurations) do not include septal anchoring elements but rather include anchoring elements which are designed for anchoring the device within a lumen of an anatomic valve as is clearly described in column 10, lines 58-63 of Bailey et al. which state:

"The CC valve stent 40 has both a proximal anchor flange 44 and a distal anchor flange 42 which are formed of sections of the stent body member 12 which project radially outward away from the central longitudinal axis of the CC valve stent 40 at opposing ends of the stent body member 12"

Such radially disposed anchors are designed for applying an outwardly projected force which is used to secure a stent valve against the walls that define the lumen of the anatomic valve. It will be appreciated that such an anchoring configuration cannot be used for anchoring a device across a septum.

The Examiner has also rejected claims 49 and 50 under 35 U.S.C. 102(b) as being anticipated by King et al. (U.S. Patent No. 3,874,388).

The Examiner states that King et al. disclose a shunt implanted between a left and a right atrium and as such King et al. would perform the steps recited in these claims.

A shunt is defined as "a hole or passage which moves, or allows movement of fluid from one part of the body to another". The presently claimed method involves implantation of a shunt into a heart septum in order to facilitate movement of blood from one chamber to another.

King et al. do not describe implantation of a shunt or any element that has a shunt-like function simply because the purpose of the King et al device is to correct septal defects.

To further differentiate the present invention as claimed, Applicant has now Amended Claim 49 to recite the following:

"implanting a shunt between a left atrium and a right atrium of the heart, thereby enabling blood flow between said left atrium and said right atrium and decreasing blood pressure in an atrium"

King et al. do not describe or suggest the present invention as now claimed in amended claim 49.

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Claim Rejections - 35 USC § 103

The Examiner has rejected claims 72, 88, 97 and 103 under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Wolf et al. (U.S. Patent No. 6,641,610).

The Examiner has also rejected claims 104-108 as being unpatentable over Bailey et al./Wolf et al. (U.S. Patent No. 6,641,610) and further in view of Cosman (U.S. Patent No. 4,787,886).

As is argued hereinabove, Bailey et al. do not describe nor suggest the presently claimed device and method. Wolf et al. merely describe a controllable valve while Cosman describes a pressure sensor which the Examiner suggests can be used in combination with the device of Bailey et al.

Since the teachings of Wolf et al. and Cosman are not relevant to the use and function of the septal configuration of Bailey et al. (which includes an occluder element and not a valve), Applicant is of the opinion that the present invention as claimed is patentable over the combined teachings of Bailey et al. and Wolf et al. or Bailey et al./Wolf et al. and Cosman.

In view of the above amendments and remarks it is respectfully submitted that claims 49-51, 59, 60, 68-73, 78, 84, 86-89, 92 and 97-108 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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